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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,653	02/09/2001	Pankaj Qasba	640100-407	7921

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

**Advisory Action**

Application No.

09/780,653

Applicant(s)

QASBA ET AL.

Examiner

Joseph T. Voitach

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 12 July 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 4 and 5.

Claim(s) withdrawn from consideration: 1-3, 7 and 8.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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AU1632

Continuation of 2. NOTE:

The proposed amendment to claims 4 and 5 to recite "and purified" raises new issues regarding the metes and bounds of what is considered 'purified' versus isolated as previously claimed. Applicants do not point to the specific support in the specification for the amendment and may raise issues regarding new matter in the context of the claimed invention. Further, a new search of the relevant art would be required regarding the ability to 'purify' such stem cells and the anticipation and/or obviousness of the additional method step in the context of the claimed invention.

In addition, the amendment to the specification requested in the transmittal of New Application papers (as indicated on page 6) has been made. Examiner apologizes for the oversight of the office regarding this amendment.

Continuation of 5. does NOT place the application in condition for allowance because:

With respect to the rejection made under 35 USC 102, the amendment to claim to comprise the additional step of purifying stem cells has not been entered, thus Applicants arguments are not applicable to the instant claims. Alternatively, given the potential breadth of the term purify, the isolation protocols used by Lemoli et al. may be considered a purification process from the individual and still anticipate the claims. Please note that as indicated above, a complete analysis would require a new search and consideration.

With respect to the rejection made under 35 USC 112, first paragraph, Applicants argue that Examiner's claim interpretation is too broad and incorrect, and that no specific evidence has been provided to demonstrate the claimed invention would not work and thus has not met the legal burden. Applicant's arguments have been fully considered, but not found persuasive. Specifically, with regard to claim interpretation Applicants have failed to demonstrate why the claim interpretation is incorrect. Examiner notes that embodiments taught in the specification can be used to interpret the claims, however they are not to be used or read as limitations to the claims. In this case, Examiner has given a reasonable interpretation of the claims and provided evidence of non-enabled in vitro embodiments recognized in the art. Further, as acknowledged in Applicants arguments it is the CD34 positive cells that differentiate into megakaryocytes, thus the absence of these cells from a patient would not result in any form of treatment indicating another non-enablement embodiment directly applicable to claim 4. Additionally, it was noted in the basis of the rejection that there was no specific guidance to what disease/patient in which to practice the claimed methods, nor any clear guidance for amounts of cells or means of delivery to affect any form of treatment. Working examples are just one factor to be considered under the guidance of Wands, Examiner acknowledges that working examples are not required, however given the non-enabled embodiment recognized in the art, lack of specific guidance to practice the invention as claimed, the unpredictability of the art of cell transplantation Examiner has made sound scientific arguments for the scope of enablement rejection over the breadth of the claimed invention.